7.01.154	Ablation of Peripheral Nerves to Treat Pain		
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Section:	7.0 Surgery	**Page:**	Page 1 of 26

Policy Statement

Radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered **investigational**.

Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered **investigational**.

Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered **investigational**.

Ablation of peripheral nerves to treat pain is considered **investigational** in all other conditions, with the exception of facet joint pain.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding
Radiofrequency treatment is considered a neurolytic agent by CPT. The following codes would be reported for radiofrequency ablation of a peripheral nerve.

- **64640:** Destruction by neurolytic agent; other peripheral nerve or branch

The following codes represent genicular nerve block procedures which have recently emerged as an alternative treatment for chronic knee pain.

- **64454**: Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
- **64624**: Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed

CPT instructs that pulsed radiofrequency treatment is reported with an unlisted code.

Description

Radiofrequency ablation (RFA) and cryoneurolysis of nerves have been proposed as treatments for several different types of pain. RFA has been used to treat a number of clinical pain syndromes such as trigeminal neuralgia as well as cervical and lumbar pain. This review evaluates the application of RFA and cryoneurolysis in peripheral sites distant from the spine.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

A number of RF generators and probes for the peripheral nervous system have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Some examples are listed in Table 1.

In 2017, the COOLIEF Cooled Radiofrequency Probe (Avanos, previously known as Halyard Health) was cleared for marketing by the FDA through the 510(k) process to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue (K163461). One of the indications is specifically for "creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response (≥ 50% reduction in pain) to a diagnostic genicular nerve block."

Table 1. Radiofrequency and Cryoneurolysis Devices

Device	Manufacturer	Clearance	Date	FDA Product Code
SInergy®/Bayless Pain Management Probe	Kimberly-Clark/Baylis	K053082	2005	GXD
NeuroTherm® NT 2000	NeuroTherm	K111576	2011	GXD
iovera	Myoscience	K133453	2014	GXH
COOLIEF® Cooled Radiofrequency Kit	Avanos, previously known as Halyard Health	K163236	2016	GXI
COOLIEF® Cooled RF Probe	Avanos, previously known as Halyard Health	K163461	2017	GXI
Rulo(TM) Radiofrequency Lesion Probe	Epimed International	K190256	2019	GXI

Rationale

Background

Knee Osteoarthritis

Knee osteoarthritis (OA) is common, and often the cause of substantial disability. Among U.S. adults, the most common causes of disability are arthritis and rheumatic disorders.

Treatment

Treatment for OA of the knee aims to alleviate pain and improve function. However, most treatments do not modify the natural history or progression of OA and are not considered curative. Nonsurgical modalities used include exercise; weight loss; various supportive devices; acetaminophen or nonsteroidal anti-inflammatory drugs (e.g., ibuprofen); nutritional supplements (glucosamine, chondroitin); and intra-articular viscosupplements. Corticosteroid injection may be considered when relief from nonsteroidal anti-inflammatory drugs is insufficient, or the patient is at risk of gastrointestinal adverse events. If symptom relief is inadequate with conservative measures, invasive treatments may be considered. Total knee arthroplasty is an operative treatment for symptomatic OA of the knee.

Plantar Fasciitis
Plantar fasciitis is a common cause of foot pain in adults, characterized by deep pain in the plantar aspect of the heel, particularly on arising from bed. While the pain may subside with activity, in some patients the pain persists and can impede activities of daily living. On physical examination, firm pressure will elicit a tender spot over the medial tubercle of the calcaneus. The exact etiology of plantar fasciitis is unclear, although a repetitive injury is suspected. Heel spurs are a common associated finding, although it has never been proven that heel spurs cause the pain. Asymptomatic heel spurs can be found in up to 10% of the population.

Treatment
Most cases of plantar fasciitis are treated with conservative therapy, including rest or minimization of running and jumping, heel cups, and nonsteroidal anti-inflammatory drugs. Local steroid injection may also be used. Improvement may take up to 1 year in some cases.

Occipital Neuralgia
Occipital neuralgia is a specific type of headache that is located on one side of the upper neck, back of the head, and behind the ears, and sometimes extending to the scalp, forehead, and behind the eyes. The pain, which may be piercing, throbbing, or electric-shock-like, follows the course of the greater and lesser occipital nerves. Occipital neuralgia is believed to occur due to pressure or irritation to the occipital nerves, which may result from injury, entrapment by tight muscles, or inflammation.

Treatment
Treatment may include massage and rest, muscle relaxants, nerve blocks, and injection of steroids directly into the affected area.

Cervicogenic Headache
Cervicogenic headache is a headache that is secondary to a disorder of the cervical spine. The pain may be referred from facet joints, intervertebral discs, or soft tissue. The pain is constant rather than throbbing, and may be aggravated by movements of the neck or pressure to certain areas on the neck. The first 3 cervical spinal nerves can refer pain to the head. The C1 suboccipital nerve innervates the atlanto-occipital joint; the C2 spinal nerve and the C3 dorsal ramus have close proximity to and innervate the C2-C3 facet joint. The C2-3 facet joint is the most frequent source of a cervicogenic headache. A diagnosis of a cervicogenic headache may be confirmed by an anesthetic block of the lateral atlanto-axial joint, the C2-3 facet joint, or the C3-4 facet joint.

Treatment
Treatment may include nerve blocks, physical therapy, and exercise.

Nerve Radiofrequency Ablation
Nerve radiofrequency ablation (RFA) is a minimally invasive method that involves the use of heat and coagulation necrosis to destroy tissue. A needle electrode is inserted through the skin and into the tissue to be ablated. A high-frequency electrical current is applied to the target tissue and a small sphere of tissue is coagulated around the needle by the heat generated. It is theorized that the thermal lesioning of the nerve destroys peripheral sensory nerve endings, resulting in the alleviation of pain. Cooled RFA is a variation of nerve RFA using a water-cooled probe that applies more energy at the desired location without excessive heat diffusing beyond the area, causing less tissue damage away from the nerve (see Table 2). The goal of ablating the nerve is the same.

RFA is also distinguished from pulsed radiofrequency (RF) treatment, which has been investigated for different types of pain. The mechanism of action of pulsed RF treatment is uncertain but it is thought not to destroy the nerve.[1,] It does produce some degree of nerve destruction but is thought to cause less damage than standard RFA. Some studies refer to pulsed RF treatment as ablation.

For the indications assessed in this evidence review, nerve RFA should be distinguished from RF energy applied to areas other than the nerve to cause tissue damage. Some patients have been treated for plantar fasciitis with a fasciotomy procedure using an RF device. This procedure does not ablate a specific nerve.

Table 2. Types of Radiofrequency Ablation

Type	Procedure	Tissue Temperature	Key Differences
Standard RFA	Electrode tip provides thermal energy for 90 – 130 seconds	70 – 90° C	Longer term pain relief but with more adjacent thermal tissue injury and limitation in size and shape of lesion.
Pulsed RFA	Non-ablative - provides 20 ms pulses every 30 seconds	42° C	Limits tissue damage but results in shorter duration of pain relief
Cooled RFA	Water circulates through RF electrode to cool the tip	60° C	Larger lesion with limited thermal injury to tissue. Longer term pain relief.

RF: radiofrequency; RFA: radiofrequency ablation
Adapted from Oladeji et al (2019)[2].

Cryoneurolysis
Cryoneurolysis is being investigated to alleviate pain. Temperatures of -20° to -100°C applied to a nerve cause Wallerian (anterograde axonal) degeneration, with disruption of nerve structure and conduction but maintenance of the perineural and epineural elements of the nerve bundle. Wallerian degeneration allows complete regeneration and recovery of nerve function in about 3 to 5 months. The iovera° cryoablation system is a portable handheld device that applies percutaneous and targeted delivery of cold to superficial peripheral nerves.

Literature Review
This review includes indications for heel pain due to plantar fasciitis and knee pain due to osteoarthritis. This review also evaluates the evidence for radiofrequency ablation (RFA) of a occipital neuralgia and cervicogenic headache. RFA and cryoneurolysis of other peripheral nerves are not addressed in this review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Radiofrequency Ablation for Knee Osteoarthritis
Clinical Context and Therapy Purpose
The purpose of RFA in patients with knee osteoarthritis (OA) who have severe refractory pain is to provide a treatment option that is an alternative to intra-articular injections or total joint replacement. Pain in OA can be transmitted via the genicular sensory nerves, which are

branches of the femoral, tibial, peroneal, saphenous, and obturator nerves around the knee.[2,] The genicular nerve branches can be divided into a 4 quadrant system —superomedial, superolateral, inferomedial, and inferolateral. Nerves in the superomedial, superolateral, and inferomedial quadrants are located near the periosteum, but the inferolateral branch is close to the peroneal nerve and is usually avoided. The exact neuroanatomy around the knee is variable and can also be affected by chronic OA. Although the location of the target nerves is aided by palpating the bony landmarks and fluoroscopy, variability may prevent the exact localization. Diagnostic nerve blocks have been evaluated to confirm the location of the genicular nerves and predict efficacy. In addition to the genicular nerves, studies have reported RFA of the saphenous nerve, the sciatic nerve, the femoral, tibial, saphenous nerves, and peripatellar plexus in combination, and the intra-articular joint space.[3,]

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in patients with knee OA?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with knee OA.

Interventions
The therapy being considered is RFA of the superomedial, inferomedial, and superolateral genicular nerves. Due to the variable location of the genicular nerves, it is thought that the increased area of denervation associated with cooled-RFA may be more effective than standard or pulsed RFA

Comparators
The following therapy is currently being used to treat OA: conservative management, which may include analgesics, physical therapy, or intra-articular injections.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured with a 10 cm visual analog scale (VAS) or 11 point numeric rating scale (NRS).

The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome. Quantifiable pre- and posttreatment measures of functional status are also used, such as the12-Item and 36-Item Short-Form Health Survey.

The Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) is also frequently used to evaluate pain and function due to OA. The WOMAC includes 3 subscales: pain, stiffness, and physical functioning. Scores range from 0 to 96, with higher scores indicating greater disability.

The Lysolm Knee Score (LKS) has 8 domains to assess limitations in function, including limp, use of supports, locking, instability, pain, swelling, stair-climbing, and squatting. Scores range from 0 to 100, with lower scores indicating greater disability.

Because of the variable natural history of OA and the subjective nature of the outcome measures, RCTs are needed to determine whether outcomes are improved with interventions for pain. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures when possible, and define a priori the clinically significant magnitude of response.

The effect of RFA is likely to be transient, so the period for follow-up is within a month to determine procedural success and adverse effects and at least 1 year to evaluate durability.

Longer follow-up would be needed to evaluate whether denervation of sensory nerves of the knee could have adverse long-term effects on knee anatomy in patients with OA.

Study Selection Criteria

We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months outcomes, and systematic reviews of RCTs. It is preferred to have double-blinded sham interventions to control for placebo effects.
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Review of Evidence

Systematic Reviews

Characteristics of systematic reviews are described in Tables 3 and 4.

Chen et al (2021) conducted a systematic review of RFA for the treatment of knee OA.[4] The authors (including several affiliated with the American Academy of Orthopaedic Surgeons) identified 7 RCTs published through 2019 that met inclusion criteria. Quality of the studies was assessed based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology for risk of bias of randomization, allocation concealment, blinding, incomplete data, selective reporting, and other bias. Five of the trials were rated as high quality[5,6,7,8,9] despite lack of blinding in most and moderate risk of bias for allocation concealment and other bias. Two [10,11] were rated as moderate quality. A majority of the studies were conducted outside of the U.S., with a number of participants ranging from 24 to 151. Techniques included RFA and cooled RFA. RFA was compared to non-treated controls or sham procedures, intra-articular corticosteroids, or hyaluronic acid. There was high heterogeneity due to the variability in comparators and outcome measures that limited meta-analysis, but analysis of the mean differences for the individual studies showed general agreement that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6 month follow-up.

The trials by Davis et al (2018), El-Hakeim et al (2018) and Xiao et al (2018) with 6 month follow-up, along with later RCTs that are not included in the systematic review, are described in greater detail below.

Table 3. Systematic Review Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Chen et al (2021)[4]	1966 - 2019	7	Patients with OA of the knee who were treated with RFA or C-RFA		RCT	up to 12 months

OA: osteoarthritis; RFA: radiofrequency ablation; C-RFA: cooled radiofrequency ablation; RCT: randomized controlled trial.

Table 4. Comparison of RCTs Included in the Systematic Review by Chen et al (2021)

Study	Trial Size	Prognostic Block	RF Method	Comparator	Follow-up	Limitations
Choi et al (2011)[5]	38	Yes	RFA	Sham	3 months	Short follow-up
Shen et al (2017)[10]	54		RFA	Standard Treatments	3 months	Short follow-up
Sari et al (2018)[6]	73	No	RFA	IA Steroid	3 months	Short follow-up
Davis et al (2018)[8]	151	Yes	C-RFA	IA Steroid	6 months	Patients not blinded

Study	Trial Size	Prognostic Block	RF Method	Comparator	Follow-up	Limitations
El-Hakeim et al (2018)[9]	60	No	RFA	Acetaminophen and NSAIDs	6 months	Patients not blinded
Ray et al (2018)[7]	24	Yes	RFA	IA Hyaluronic Acid	3 months	Short follow-up
Xiao et al (2018)[11]	96	No	RFA	IA Hyaluronic Acid	6 months	Patients not blinded

C-RFA: cooled radiofrequency ablation; IA: intra-articular; NSAIDS: nonsteroidal anti-inflammatory drug; RCT: randomized controlled trial; RFA: radiofrequency ablation.
Table adapted from Jamison and Cohen (2018) [3]

Randomized Controlled Trials

Characteristics and results of randomized controlled trials are described in Tables 5 and 6.

El-Hakeim et al (2018) reported a single-center RCT that compared RFA of the genicular nerves to conventional analgesics in 60 patients with Kellgren-Lawrence stage III or IV knee OA.[9] The investigators did not use a positive response to nerve blocks to determine who to treat but did assess the accuracy of the target by sensory and motor responses to stimulation. The best approach to identify the genicular nerves is uncertain.[12] VAS pain scores decreased from baseline in both groups and were significantly lower in the RFA group from 2 weeks to 6 months after treatment. WOMAC scores, which were assessed by a clinician who was blinded to treatment, were significantly better only at the 6 months time point.

Davis et al (2018) reported on a multicenter randomized trial comparing cooled RFA to corticosteroid injection in 151 patients who had chronic (>6 months) knee pain unresponsive to conservative therapy.[8] At 1 month after treatment, both groups showed a reduction in pain, with a 0.9-point difference on an 11-point NRS. By 3 months after treatment, pain scores had increased in the steroid group, while pain scores in the RFA group remained low throughout the 6 month follow-up. At the 6-month follow-up, 74.1% of patients in the RFA group were considered responders (≥50% decrease in the NRS), compared with 16.2% of patients treated with steroid injections (p<.001). Twelve month follow-up was reported in 2018.[13] Out of the 76 patients randomized to RFA, 52 (68%) patients were available for follow-up at 12 months. Out of those 52, 34 (65%) reported at least a 50% decrease in pain on an NRS. Limitations of this observational portion of the study include the 32% loss to follow-up and the lack of blinding for this subjective measure. All but 4 of the patients in the intra-articular steroid arm had crossed over to cooled RFA by the 12-month follow-up.

Twelve to 24 month follow-up of a subset of patients treated with RFA in the RCT by Davis et al (2018) was reported by Hunter et al (2020) and is shown in Table 7.[8,14] There were 42 patients randomized to RFA and 41 randomized to the control group who crossed over to RFA at 6 months who qualified for follow-up at participating sites. Of the 83 potential participants, 15 had additional procedures (e.g. steroid injection, total knee arthroplasty, hyaluronic injection, repeat RFA) and were not included in the analysis, 35 (42.2%) could not be reached or declined to participate, and 33 (40%) consented for the study. Although 44% of patients who participated in follow-up maintained their improvement in pain scores, this was a small percentage of the patients who received treatment. Interpretation is limited due to the small number of patients and the potential for bias in this non-blinded study.

Another manufacturer-sponsored trial on cooled RFA for knee osteoarthritis was reported by Chen et al (2020).[15] The investigators randomized 177 patients to RFA or a single injection of hyaluronic acid (Synvisc ONE). Although widely used, the efficacy of hyaluronic acid has not been supported by evidence.[16] Therefore, it might be considered a placebo treatment. Crossovers to RFA (n=68, 82.9%) were allowed at 6 months. A major limitation of this publication is that results were reported only for the 83% of control patients who crossed over; the authors noted that the remainder of the patients reported long-term pain relief from hyaluronic acid.

An independent study by Elawamy et al (2021) compared pulsed radiofrequency to a single injection of platelet-rich plasma in 200 patients with OA (NCT03886142).[17] VAS scores showed an improvement of 50% (from a score of 6 to 3) in both groups at 3 months, with values returning to a score of 5 by the sixth month. Scores on the Index of Severity for OA of the Knee were reduced from 7 at baseline to 4 at the third month, increasing to 5 at the sixth month. Twelve month scores were not reported. Platelet-rich plasma is not considered a standard of care treatment for OA and there were a number of additional limitations in conduct and reporting of this study. Limitations of these studies, which include potential for bias due to lack of patient blinding and insufficient number of patients in follow-up, are described in Tables 8 and 9. Overall, the available studies have methodological limitations and the number of patients studied for this common condition is low.

Table 5. Summary of Key RCT Characteristics

Study	Countries	Sites	Participants	Interventions	
				Active	***Comparator***
Davis et al (2018)[8]	U.S.	11	151 patients with chronic (>6 mo) knee pain unresponsive to conservative therapy[a]; pain score ≥6; OA grades 2-4; Oxford Knee Score of ≤35; a positive diagnostic genicular nerve block[a,b]	Cooled RFA of the genicular nerves under fluoroscopic guidance (n=76)	Intra-articular steroid (n=75)
El-Hakeim et al (2018)[9]	Egypt	1	60 patient with stage III or IV knee OA	RFA of the genicular nerves under fluoroscopic guidance (n=30)	Conventional analgesics (n=30)
Xiao et al (2018)[11]	China	1	96 patients with OA with VAS >6 and LKS <60 who had abandoned other therapeutic measures	RFA of the genicular nerves guided by a plexus nerve stimulator (n=49)	Single intra-articular hyaluronic acid injection (n=47)
Chen et al (2020)[15]	U.S.	Multicenter	177 patients with knee OA	Cooled RFA of the genicular nerves under fluoroscopic guidance (n=89)	Single hyaluronic acid injection (Synvisc-One, n=88)
Elawamy et al (2021)[17]	Egypt	2	200 patients with knee OA grade III or IV refractory to conservative management	Pulsed RFA with identification of the genicular nerves based on proximity to the arteries by ultrasound and sensory stimulation (n=100)	Single intra-articular platelet rich plasma (n=100)

LKS: Lysolm Knee Score; OA: osteoarthritis; RCT: randomized controlled trial; RFA: radiofrequency ablation; VAS: visual analog score.
[a] Conservative treatment included physical therapy, oral analgesics: ≤60 mg morphine equivalence, stable for 2 months; intra-articular injections with steroids and/
or viscosupplementation), body mass index (BMI) <40, and reporting ≥50% response to blocks as
[b] At least 50% reduction in numeric rating scale for pain with anesthetic injection to the superomedial and inferomedial branches of the saphenous nerve and the superolateral branch of the femoral nerve.

Table 6. Summary of Key RCT Results

Study	Mean Pain Scores (SD)				Function	
	1 Month	*3 Months*	*6 Months*	*Responders at 6 Months, %[a]*	*Mean Oxford Knee Score at 6 Months (SD)*	*Global Perceived Effect at 6 Months, %*
Davis et al (2018)[8]	**NRS**					
N	136	132	126	126	125	126
RFA	3.0 (2.3)	2.8 (2.2)	2.5 (2.3)	74.1	35.7 (8.8)	91.4
Steroid injection	3.9 (2.2)	5.2 (2.0)	5.9 (2.2)	16.2	22.4 (8.5)	23.9
p-Value	.025	<.001	<.001	<.001	<.001	<.001
El-Hakeim et al (2018)[9]	**VAS**			**WOMAC**		
	2 Weeks	*3 Months*	*6 Months*	*2 weeks*	*3 Months*	*6 Months*
N	60	60	60	60	60	
RFA	2.47 (0.3)	2.83 (0.5)	3.13 (0.3)	93.53 (1.9)	21.67 (4.4)	24.23 (4.3)
Analgesics	3.63 (0.27)	4.93 (0.2)	5.73 (0.26)	54.07 (3.0)	30.93 (2.5)	37.1 (1.9)
p-Value	.004	<.001	<.001	.17	.10	<.001
Xiao et al (2018)[11]	**VAS**			**Lysolm Knee Score**		
	3 Days	*6 Months*	*12 Months*	*3 Days*	*6 Months*	*12 Months*
N	96	96	96	96	96	96
RFA	3.38 (1.02	2.41 (1.06)	3.12 (1.03)	78.1 (7.5)	68.3 (6.6)	84.6 (4.3)
Hyaluronic Acid	5.11 (1.13)	5.13 (1.12)	7.01 (1.01)	61.1 (5.3)	54.1 (6.2)	43.2 (6.1)
p-Value	<.05	<.05	<.05	<.05	<.05	<.05
Chen et al (2020)[15]	**NRS**				**WOMAC**	
	1 Month	*6 Months*	*12 Months*	*Responders at 6 Months, %[a]*	*6 Months*	*12 Months*
N	153	144	128	144	144	128
RFA (95% CI)	3.0 (2.5 to 3.5)	2.7 (2.2 to 3.2)	2.8 (2.2 to 3.4)	71.1%	33.6 (28.4 to 38.9)	33.2 (27.5 to 38.9)
Hyaluronic Acid	NR	NR	NR	NR	NR	NR
Subgroup of control patients who crossed over to RFA at 6 mo	4.2 (3.6 to 4.8)	5.0 (4.4 to 5.6)	3.0 (2.4 to 3.6)	29.4%	58.1 (53.4 to 62.8)	38.4 (32.7 to 44.1)
p-Value	.002	<.001	.618	<.001	<.001	.1996
Elawamy et al (2021)[17]	**VAS**			**ISK**		
	1 Week	*6 Months*	*12 Months*	*1 Week*	*6 Months*	*12 Months*
N	200	NR	NR	200	NR	NR
RFA	3	5	5	5	4	NR
Platelet-rich Plasma	3	5	6	6	6	NR
p-Value	NR	NR	NR	NR	NR	

ISK: Index of Severity for Osteoarthritis of the Knee; NR: not reported; NRS: numeric rating scale; RCT: randomized controlled trial; RFA: radiofrequency ablation; SD: standard deviation; VAS: visual analog score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.
[a] Greater than 50% reduction in the NRS.

Table 7. Extended Follow-up of Patients Treated with RFA

Study	Mean Pain Scores (SD)				Function	
	At 12 Months	*At 18 Months*	*At 24 Months*	*Responders at 18 Months, %[a]*	*Oxford Knee Score at 18 Months (SD)*	*Oxford Knee Score at 24 Months (SD)*
Davis et al (2018), Hunter et al (2020)[8,14]	NRS					
N (randomized and crossover)	30	25	18	25	25	18
RFA	3.0 (2.5)	3.1 (2.7)	3.6 (2.8)	44.0	47.2 (8.1)	46.8 (10.3)

NRS: numeric rating scale; RFA: radiofrequency ablation; SD: standard deviation;
[a] Greater than 50% reduction in the NRS.

Table 8. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Davis et al (2018)[8.]					1. Follow-up >6 mo is needed to evaluate durability of the procedure. Extended follow-up is in progress (see Table 18).
El-Hakeim et al (2018)[9.]	4. Patients were not selected by a positive response to a nerve block		2. Controls received only analgesics and physical therapy if needed		1. Follow-up >6 mo is needed to evaluate durability of the procedure
Xiao et al (2018)[11.]	4. Patients were not selected by a positive response to a nerve block		2. Efficacy of a single injection of hyaluronic acid as an active comparator is not supported by evidence		
Chen et al (2020)[15.]			2.. Efficacy of a single injection of hyaluronic acid as an active comparator is not supported by evidence		
Elawamy et al (2021)[17.]	4. Patients were not selected by a positive response to a nerve block	1. Both groups received analgesics and physical therapy, but these were not recorded.	2. Efficacy of a single injection of platelet-rich plasma as an active comparator is not supported by evidence		

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 9. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Davis et al (2018)[8.]		1. Patients were not blinded to treatment assignment, which might have affected subjective scores		1. Unequal loss to follow-up 3. Crossovers to RFA were allowed at 6 mo		2. The study used Wilcoxon signed-rank sum test rather than a repeated-measures test
El-Hakeim et al (2018)[9.]	2. Allocation concealment not described	1. Patients were not blinded to treatment				2. The study did not use a repeated-measures

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
		assignment, which might have affected subjective scores				test for the different time points.
Xiao et al (2018)[11,]	2. Allocation concealment not described	1. Patients were not blinded to treatment assignment, which might have affected subjective scores			1. Power calculations were not reported	2. The study did not use a repeated-measures test for the different time points.
Chen et al (2020)[15,]		1. Patients were not blinded to treatment assignment, which might have affected subjective scores	2. Results were reported only for the control patients who failed treatment and crossed over			2. The study did not use a repeated-measures test for the different time points.
Elawamy et al (2021)[17,]		1. Patients were not blinded to treatment assignment, which might have affected subjective scores		6. It is unclear how many patients completed the 12 month follow-up		2, 4. The study did not use a repeated-measures test and there was no comparison between groups.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
RFA: radiofrequency ablation.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Observational Studies

Observational studies can provide information on durability that is not available from RCTs (Tables 10 and 11). Follow-up to 12 months was reported by Santana Pineda et al (2017) in a

prospective study of 25 patients.[18] The response rate was 88% at 1 month after treatment, decreasing to 64% at 6 months and 32% at 12 months.

Kapural et al (2019) reported a retrospective assessment of pain relief in 183 out of 205 (86%) patients who had been treated with RFA of the genicular nerves and returned for evaluation.[19] At follow-up (time not reported), 65% of patients reported greater than 50% pain relief and 77% had a decrease in VAS of at least 2 points. The average duration of reported pain relief was 12.5 months (range, 0 to 35 months). Opioid use was not reduced, but this result is confounded because 80% of patients reported at least 1 additional source of chronic pain (e.g., back, shoulder). The publication notes that pain scores were assessed at 3 and 6 months and at the latest visit, but is unclear about the range of follow-up and the time of the reported results.

These observational studies suggest that between one-third and two-thirds of patients will continue to report at least a 50% reduction in pain at 12 months following RFA of the genicular nerves.

Table 10. Summary of Key Case Series Characteristics

Study	Country	Participants	Treatment Delivery	Follow-Up
Santana Pineda et al (2017)[18]	E.U.	25 patients with grade III-IV knee OA (n=24) or after total knee arthroplasty (n=1) and intractable pain with VAS ≥5 for >6 mo	RFA of superior medial, superior lateral, and inferior medial genicular nerves with electrode tips placed on periosteal areas and guided by ultrasound and neurostimulation	12 mo
Kapural et al (2019)[19]	U.S.	205 patients with knee pain (21 had pain after TKA) who had a positive response to a geniculate block and underwent C-RFA. Mean VAS pain prior to treatment was 8.5 and 2.2 after the nerve block	C-RFA of the geniculate nerves under fluoroscopic guidance as described in Davis et al (2018)	NR

C-RFA: cooled radiofrequency ablation; NR: not reported: OA: osteoarthritis; RFA: radiofrequency ablation; TKA: total knee arthroplasty; VAS: visual analog scale.

Table 11. Summary of Key Case Series Results

Study	Treatment	Proportion With ≥50% Improvement in pain, n/N (%) (95% CI)		
		At 1 Month	***At 6 Months***	***At 12 Months***
Santana Pineda et al (2017)[18]	RFA of genicular nerves	22/25 (88%)	16/25 (64%)	8/25 (32%)
Kapural et al (2019)[19]	C-RFA of genicular nerves	NR	NR	65% at a mean of 12.5 months (range, 0 to 35)

CI: confidence interval; C-RFA: cooled radiofrequency ablation ; NR: not reported; RFA: radiofrequency ablation.

Safety

In 2021, the Spine Intervention Society's Patient Safety Committee published an article on the safety of genicular nerve RFA.[20] The committee reviewed case reports of septic arthritis, pes anserine tendon injury, third-degree skin burn, and clinically significant hematoma and/or hemarthrosis with RFA of the genicular nerves, concluding that larger cohort studies are needed to determine the incidence of these complications for this emerging technology.

Section Summary: Radiofrequency Ablation for Knee Osteoarthritis

Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. To date, the evidence on RFA for knee pain includes systematic reviews of RCTs, RCTs with 24 to 200 patients (including 4 with a minimum of 6-month follow-up), and prospective observational studies with 12 to 24 months of follow-up. The systematic review found high

heterogeneity due to the variability in type of RFA used, comparators and outcome measures that limited meta-analysis, but analysis of the mean differences for the individual studies showed general agreement that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3 and 6 month follow-up. Trials have compared RFA to sham procedures, intra-articular steroid injection, intra-articular hyaluronic acid injection, and platelet-rich plasma injection. Although intra-articular steroid injection is an established treatment for OA pain, it has limited durability. The efficacy of hyaluronic acid has been challenged and that of platelet-rich plasma is uncertain so it is unclear whether these would be considered active or placebo controls. Few of the studies were blinded, which may have biased the subjective outcome measures. Additional limitations in design and conduct include suboptimal statistical analyses and reporting of loss to follow-up. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate above 70% at 6 months which was significantly greater than the control conditions. Given that OA of the knee is a common condition, study in a larger number of patients, preferably in blinded studies with active and sham controls and follow-up of at least 12 months is needed to determine the benefits and potential harms of this treatment.

Cryoneurolysis for Knee Osteoarthritis or Total Knee Arthroplasty
Clinical Context and Therapy Purpose
The purpose of cryoneurolysis in patients who have OA or TKA is to provide a treatment option that is an alternative to standard therapies. Pain control in patients with knee OA can delay TKA, while pain control following TKA is essential for patients to participate in physical therapy and promote recovery.

The question addressed in this evidence review is: Does the use of cryoneurolysis improve the net health outcome in patients with OA or following TKA?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with OA or who have undergone TKA.

Interventions
The therapy being considered is percutaneous cryoneurolysis of the anterior femoral cutaneous nerve and/or the infrapatellar branch of the saphenous nerve.

Comparators
The following therapies are currently being used to treat OA or pain with TKA: conservative management, which may include corticosteroid injection or oral medications, for OA, and opioid or peripheral nerve blocks with anesthetics, for TKA.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or NRS. The Oxford Knee Score is scaled between 12 and 60, with 12 representing the best outcome. Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey. The WOMAC score is also frequently used to evaluate function due to OA. The time for follow-up is within days to determine procedural success and at least 6 months to a year to evaluate durability.

Study Selection Criteria
We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months outcomes, and systematic reviews of RCTs

- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Randomized Controlled Trials

Radnovich et al (2017) reported a double-blind multicenter RCT of cryoneurolysis for patients with mild-to-moderate OA (Table 12).[21] Compared with sham-treated patients, cryoneurolysis resulted in a greater decrease in WOMAC pain score, WOMAC total score, and VAS score at 30 days (Table 13). The cryoneurolysis group also had better WOMAC total scores at 90 days but not at 60 days. Improvements in VAS scores did not differ significantly between active and sham treatment groups at 60 and 90 days.

Table 12. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Radnovich et al (2017)[21]	U.S.	17	2013-2016	180 patients with mild-to-moderate (grade II-III) knee OA with knee pain ≥40 mm/100-mm VAS and ≥50% reduction in pain on diagnostic block	n=121 percutaneous cryoneurolysis targeting the IBSN with anatomic landmarks (visual and palpation)	n=59 sham cryoneurolysis with a sham tip and local anesthetic

IBSN: infrapatellar branch of the saphenous nerve; OA: osteoarthritis; RCT: randomized controlled trial; VAS: visual analog score.

Table 13. Summary of Key RCT Results

Study	Change in WOMAC Score (SEM)				VAS Score (SEM)		
	Pain at 30 Days	***Total at 30 Days***	***At 60 Days***	***At 90 Days***	***At 30 Days***	***At 60 Days***	***At 90 Days***
Radnovich et al (2017)[21]							
N	180	180	180	180	180	180	180
Cryoneurolysis	-16.65 (1.26)	-78.78 (5.81)	-75.75 (5.87)	-80.31 (5.89)	-40.09 (2.87)	-38.53 (2.91)	-37.90 (3.01)
Sham	-9.54 (1.63)	-48.26 (7.51)	-56.28 (7.58)	-56.51 (7.60)	-27.83 (3.68)	-32.44 (3.73)	-31.58 (3.86)
Diff (95% CI)	-7.12 (-11.01 to -3.22)	-30.52(-48.52 to -12.53)	-19.47(-37.64 to -1.30)	-23.80(-42.02 to -5.57)	-12.25(-21.16 to -3.35)	-6.09(-15.11 to 2.94)	-6.32(-15.66 to 3.01)
p	.004	.001	.036[a]	.011	.007	.185	.183

CI: confidence interval; Diff: difference; RCT: randomized controlled trial; SEM: standard error of mean; VAS: visual analog score; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.
[a] Statistical significance was set at a 1-sided level of 0.025.

Tables 14 and 15 display notable limitations identified in the studies evaluated.

Table 14. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Radnovich et al (2017)[21]	4. A more relevant population would be patients with moderate-to-severe knee osteoarthritis				

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 15. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Radnovich et al (2017)[21]						2. Unclear whether data were modeled for each time point independently or longitudinally

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Technical Issues
As noted in a review by Gabriel and Ilfeld (2018), several technical issues have yet to be resolved, including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula.[22] The most effective method for determining the location of the probe (e.g., ultrasound or using anatomic landmarks) also needs to be established.

Section Summary: Cryoneurolysis for Knee Osteoarthritis
An RCT with 180 patients has compared cryoneurolysis with sham treatment in patients who had knee OA. Cryoneurolysis resulted in a greater decrease in WOMAC pain, WOMAC total, and VAS score at 30 days compared with sham-treated controls. Subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or in VAS scores at 60 or 90 days. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula, have yet to be resolved.

Radiofrequency Ablation for Plantar Fasciitis
Clinical Context and Therapy Purpose
The purpose of RFA in patients who have plantar fasciitis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of RFA improve the net health outcome in patients with plantar fasciitis?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with plantar fasciitis.

Interventions
The therapy being considered is RFA.

Comparators
The following therapy is currently being used to make decisions about treating plantar fasciitis: conservative management, which may include corticosteroid injection.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is a subjective, patient-reported measure. Therefore, pain outcomes require quantifiable pre- and posttreatment measures. Pain is most commonly measured using a VAS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the American Orthopedic Foot and Ankle Society (AOFAS) ankle-hindfoot score. The AOFAS ankle-hindfoot scores range from 0 to 100, with up to 40 points for pain, 50 points for functional aspects, and 10 points for alignment. A high score indicates a better outcome. The time for follow-up is within days to determine procedural success and at least 6 months to a year to evaluated durability.

Study Selection Criteria
Because of the variable natural history of plantar fasciitis and the subjective nature of the outcome measures, RCTs are needed to determine whether outcomes are improved with interventions for pain. Trials should include a homogenous population of patients with a defined clinical condition, use standardized outcome measures when possible, and define a priori the clinically significant magnitude of response.

Review of Evidence
Randomized Controlled Trials
Two double-blind sham-controlled randomized trials have assessed RFA for the treatment of chronic heel pain (Table 16). Wu et al (2017) randomized 36 patients to ultrasound-guided pulsed radiofrequency of the posterior tibial nerve.[23] First step pain, average pain, and the AOFAS ankle-hindfoot score were assessed at baseline and at 1, 4, 8, and 12 weeks. Scores at 12 weeks are shown in Table 14. Changes in VAS score in the sham group were modest (<1 on a 10-point VAS) and of short duration (statistically significant at weeks 1 and 4 but not weeks 8 and 12). The AOFAS ankle-hindfoot score was 60.55 at baseline and 60.05 at 12 weeks in the sham group. In the RFA group, VAS scores at weeks 1, 4, 8, and 12 were all significantly lower than baseline (p<.001), and the AOFAS ankle-hindfoot score increased from 55.5 to 87.6 (p<.001). The improvements in pain and function were greater in the RFA group than in the control group (p<.001 for all measures).

Landsman et al (2013) reported on a double-blind randomized crossover trial of RFA applied along the medial aspect of the heel.[24] Crossover to the alternate treatment was allowed at 4 weeks. Outcomes assessed weekly were a pain VAS score reported at the first step in the morning, average pain level, and peak pain level (Table 17). In a graphic presentation of results, patient pain levels for all 3 outcomes decreased after RFA but showed minimal change after sham. After patients crossed over from sham to RFA, there was a steep drop in all pain outcomes. The maximum follow-up assessment was at 16 weeks and appeared to show similar pain levels throughout the follow-up period.

Table 16. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	***Comparator***
Wu et al (2017)[23]	Taiwan	1	2014-2016	36 patients (40 feet) with recalcitrant plantar fasciitis	Ultrasound-guided pulsed RF stimulation of the posterior tibial nerve	Sham with ultrasound-guided lidocaine injection

Study	Countries	Sites	Dates	Participants	Interventions	
Landsman et al (2013)[24.]	U.S.	Multicenter	NR	17 patients failed at least 3 prior types of treatments, pain for >3 mo, and VAS score ≥5	RFA procedure, including stimulation of sensory nerves in an awake patient	Sham with all aspects of the RFA procedure, except delivery of RF energy at the final step

NR: not reported; RCT: randomized controlled trial; RF: radiofrequency; RFA: radiofrequency ablation; VAS: visual analog scale.

Table 17. Summary of Key RCT Results

Study	First Step Pain on VAS Score	Average VAS Pain Score		AOFAS Ankle-Hindfoot Score
	At 12 Weeks	***At 12 Weeks***		
Wu et al (2017)[23.]				
N	36	36		36
RFA (SD)	1.79 (1.62)	1.54 (1.26)		87.60 (9.12)
Sham (SD)	6.13 (1.75)	6.09 (1.70)		60.05 (11.38)
	Change At 4 Weeks	Change Score	Change in Peak Pain	
Landsman et al (2013)[24.]				
N	17	17	17	
RFA	5.0	4.06	5.33	
Sham	1.33	0.8	1.80	
p	.30	.047	.048	

AOFAS: American Orthopedic Foot and Ankle Society; RCT: randomized controlled trial; RFA: radiofrequency ablation; SD: standard deviation; VAS: 10-cm visual analog score.
Tables 18 and 19 display notable limitations identified in each study.

Table 18. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-Up[e]
Wu et al (2017)[23.]	3. Study did not report a minimum VAS for inclusion criteria				
Landsman et al (2013)[24.]		1. Targeted nerve not clearly defined			1. Crossover allowed at 4 wk

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
VAS: visual analog score.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 19. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Follow-Up[d]	Power[e]	Statistical[f]
Wu et al (2017)[23.]						
Landsman et al (2013)[24.]				3. Crossovers at 4 wk prevented longer-term assessments	1. Power calculations not reported	3. Confidence intervals not reported

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Follow-Up key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Intervention is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Intervention is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4.Comparative treatment effects not calculated.

Case Series
The largest case series with the longest follow-up is by Cozzarelli et al (2010).[25] This study reported on a 12-year follow-up of 82 patients who had undergone RFA for heel pain. Patients had undergone RFA between 1994 and 1995 and had been interviewed at 5, 10, and 12 years postprocedure. Baseline pain levels before the procedure were recalled retrospectively at the follow-up interviews. Of 99 patients potentially eligible to be interviewed, the study evaluated 82 patients. The results were presented without statistical testing. It appears that 73 of 82 patients reported being pain-free at 12 years. On a 0-to-10 pain VAS, the pain-free patients rated their preprocedure pain at a mean of 7.1 and at 0 postprocedure.

Cione et al (2009) reported on a retrospective case series of 75 patients treated with RFA.[26] Patients who underwent RFA between 2000 and 2003 were surveyed in 2004 to assess preprocedure and current pain status. In this series, the actual number of treated patients is unknown, and preprocedure pain status was assessed only at the follow-up survey. Median preprocedure pain VAS was 9 (range, 2-10) and the postprocedure pain VAS was 1 (range, 0-8; p<.001).

Section Summary: Plantar Fasciitis
Two randomized, double-blind trials and several case series have shown consistent reductions in pain after RFA for patients with heel pain due to plantar fasciitis. However, several case series had methodologic weaknesses. In 2 of them, all pain assessments were performed retrospectively, including pretreatment pain assessment. The 2 randomized trials enrolled few subjects. Due to crossover at 4 weeks in 1 of the trials, the randomized comparison only evaluated outcomes to 4 weeks. To be more confident in the efficacy of this treatment, studies with larger samples and longer follow-up would be necessary. The safety of the procedure cannot be fully evaluated in the small samples studied so far.

Radiofrequency Ablation or Cryoneurolysis for Occipital Neuralgia and Cervicogenic Headache
Clinical Context and Therapy Purpose
The purpose of RFA in patients who have occipital neuralgia or a cervicogenic headache is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of neuroablative treatments improve the net health outcome in patients with occipital neuralgia or a cervicogenic headache?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is patients with occipital neuralgia or a cervicogenic headache.

Interventions
The therapy being considered is RFA or cryoneurolysis. These treatments involve the percutaneous insertion of a catheter that is directed toward the nerve of interest, and are used to ablate the nerve by thermal lesioning.

Comparators
The following therapy is currently being used to treat occipital neuralgia or a cervicogenic headache: conservative management.

Outcomes
The most clinically relevant outcome measures for pain treatments are measures of pain severity and functional limitations. Pain is most commonly measured with a VAS or RNS. Quantifiable pre- and posttreatment measures of functional status are also used, such as the 12-Item and 36-Item Short-Form Health Survey. The time for follow-up is within days to determine the procedural success and months to years to evaluate durability.

Study Selection Criteria
We selected methodologically credible studies, using these principles:

- To assess efficacy outcomes, we sought comparative controlled prospective trials, with a preference for RCTs with a minimum of 6 months outcomes, and systematic reviews of RCTs
- To assess long-term outcomes and adverse effects, we sought single-arm studies with longer periods of follow-up and/or larger populations.
- Within each category of study design, we included studies with larger sample sizes and longer duration.

Review of Evidence
Systematic Reviews
Grandhi et al (2018) conducted a systematic review of RFA for the treatment of a cervicogenic headache.[27.] Ten studies met selection criteria, including 3 RCTs, 3 prospective studies, and 4 retrospective studies. There were no high-quality RCTs. Two of the RCTs evaluated RFA of the facet joints and failed to find a benefit of RFA. The third RCT compared RFA with steroid injection of the greater occipital nerve, finding no difference between the groups in the short term, but a longer duration of pain control in the RFA group.

A systematic review by Ducic et al (2014) did not identify any RCTs assessing RFA for chronic occipital neuralgia.[28.] Reviewers identified 3 case series (total n=131 patients) on pulsed RF treatment. Success rates in these series ranged from 51% to 100%, with an overall success rate of 55%. Follow-up ranged from 3 to 10 months.

Randomized Controlled Trials
A double-blinded RCT of 52 patients who were treated with cryoneurolysis or injection of corticosteroid and local anesthetic in a tertiary pain clinic was reported by Kvarstein et al (2019).[29.] The investigators noted a temporary benefit of both treatments for cervicogenic headache, but there was no additional benefit for the more invasive procedure. A possibility of adverse effects of repeated occipital cryoneurolysis were noted to include scar and neuroma formation and a risk of neuropathic pain.

Section Summary: Radiofrequency Ablation for Occipital Neuralgia and Cervicogenic Headache
No RCTs of RFA for chronic occipital neuralgia have been identified. A systematic review identified 3 RCTS of RFA for a cervicogenic headache, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to a placebo effect. Trials with sham or active controls are needed to evaluate the efficacy of this treatment. One RCT that compared cryoneurolysis with injection of corticosteroid and local anesthetic found no significant improvement with the more invasive treatment.

Summary of Evidence

For individuals who have knee OA who receive RFA of peripheral nerves, the evidence includes systematic reviews of RCTs, RCTs with 24 to 200 patients (including 4 with a minimum of 6-month follow-up), and prospective observational studies with 12 to 24 months of follow-up. Relevant outcomes include symptoms, functional outcomes, and QOL. Knee OA is a common disorder in older adults. RFA of the genicular nerves has the potential to alleviate pain and improve function in this population, and might also delay or eliminate the need for TKA. At this time, there is high heterogeneity in methods and comparators. The 2 multi-center trials conducted in the U.S. used anesthetic nerve block under fluoroscopic guidance and compared efficacy of cooled RFA to either steroid injection or hyaluronic acid injection. Both studies reported a responder rate approximately 70% at 6 months, which was significantly greater than the control conditions. Given that OA of the knee is a common condition; study in a larger number of patients, preferably blinded with active and sham controls and follow-up of at least 12 months, is needed to determine the benefits and potential harms of this treatment. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have knee OA or TKA who receive cryoneurolysis of peripheral nerves, the evidence includes an RCT with 180 patients and a retrospective comparative study. Relevant outcomes include symptoms, functional outcomes, and QOL. Cryoneurolysis in patients with knee OA resulted in a greater decrease in WOMAC pain score, WOMAC total score, and VAS score at 30 days compared with sham-treated controls. However, subsequent measurements showed no significant benefit of cryoneurolysis on WOMAC score at 60 days or VAS scores at 60 or 90 days. Perioperative cryoneurolysis was shown in a retrospective comparison to reduce the length of stay and opioid use in patients undergoing TKA. These results need to be confirmed in an RCT. Several technical issues including the optimal number of applications for each nerve, the duration of treatment, and the duration of thawing before moving the cannula have not been resolved. The most effective method for determining probe insertion location (e.g., ultrasound-guided or based on anatomic landmarks) also need to be established. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have plantar fasciitis who receive RFA of peripheral nerves, the evidence includes two RCTs. Relevant outcomes include symptoms, functional outcomes, and QOL. One of the randomized trials only evaluated 17 patients, and assessment of randomized outcomes was limited to 4 weeks post-treatment. A second RCT evaluated 36 patients out to 12 weeks. The case series generally had small sample sizes, and many had methodologic deficiencies such as retrospective assessment of pain. To be more confident in the efficacy of this treatment, controlled trials with larger samples and longer follow-up would be necessary. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have occipital neuralgia or cervicogenic headache who receive RFA or cryoneurolysis of peripheral nerves, the evidence includes RCTs and systematic reviews of RCTS. Relevant outcomes are symptoms, functional outcomes, and QOL. No RCTs of RFA for chronic occipital neuralgia have been identified. Three RCTs of RFA for a cervicogenic headache have been published, none of which were high quality. Pain is a subjective, patient-reported measure that is particularly susceptible to a placebo effect. Randomized trials with sham or active-controls are needed to evaluate the efficacy of this treatment. One controlled trial found a temporary benefit of cryoneurolysis for cervicogenic headache, but the effect was not significantly better than injection of corticosteroid and local anesthetic. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Orthopaedic Surgeons

The American Academy of Orthopaedic Surgeons published a clinical practice guideline on the treatment of osteoarthritis of the knee in 2013.[16] There was no assessment of the more recently developed radiofrequency ablation or cryoneurolysis of genicular nerves.

American College of Rheumatology and Arthritis Foundation

2019 Guidelines from the American College of Rheumatology and the Arthritis Foundation gave a conditional recommendation for radiofrequency ablation for the treatment of knee osteoarthritis.[30] The recommendation was based on evidence of a potential analgesic benefit, but the studies used heterogeneous techniques and there was a lack of long-term safety data.

American College of Foot and Ankle Surgeons

The American College of Foot and Ankle Surgeons (2018) issued consensus guidelines on the diagnosis and treatment of acquired infracalcaneal heel pain.[31] The safety and efficacy of bipolar radiofrequency were listed as uncertain (neither appropriate nor inappropriate).

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 18.

Table 18. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03818022	Effectiveness of Preoperative Cryoneurolysis (Iovera) for Postoperative Pain Control in Total Knee Arthroplasty	100	Dec 2020
NCT02915120	Ultrasound-Guided Pulsed Radiofrequency Of The Genicular Nerves In The Treatment Of Patients With Osteoarthritis Knee Pain: Randomized, Double-Blind, Placebo-Controlled Trial	142	Jul 2021
NCT03774121	Cryoneurolysis for the Management of Chronic Pain in Patients With Knee Osteoarthritis; A Randomized Controlled Study	90	Dec 2021
NCT04145011[a]	A Prospective, Multi-center, Randomized, Single Blind Clinical Trial Comparing COOLIEF* Cooled Radiofrequency to Conventional Radiofrequency Ablation of the Genicular Nerves in the Management of Knee Pain in an Osteoarthritic Patient Population	153	Aug 2022
Unpublished			
NCT02294864	A Controlled Comparison of Pulsed Radiofrequency Vs Physical Therapy on Treating Chronic Knee Osteoarthritis	50	Apr 2017 (unknown)

NCT No.	Trial Name	Planned Enrollment	Completion Date
NCT02260869	Efficacy of Cooled and Monopolar Radiofrequency Ablation of the Geniculate Nerves for the Treatment of Chronic Osteoarthritic Knee Pain	78	Jun 2019 (terminated due to finances)
NCT03628482[a]	A Randomized Controlled Study to Compare Efficacy of Continuous Versus Pulsed Radiofrequency Treatment of Genicular Nerves to Alleviate Pain and Improve Functional Impairment in Patients With Advanced Osteoarthritis of the Knee	188	Dec 2019
NCT02925442[a]	Comparison Between Cooled (C-RFA) and Standard (t-RFA) Radiofrequency Ablation, and Control for Pain Management Following Unilateral Knee Arthroplasty: A Double-Blinded, Parallel-Grouped, Placebo-Controlled Randomized Clinical Trial	150	Feb 2020

NCT: national clinical trial.
[a] Industry sponsored or partially sponsored.

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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed
	64624	Destruction by neurolytic agent, genicular nerve branches including imaging guidance, when performed
	64640	Destruction by neurolytic agent; other peripheral nerve or branch
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/01/2016	BCBSA Medical Policy adoption
06/01/2017	Policy revision without position change
11/01/2017	Policy revision without position change
11/01/2018	Policy title change from Radiofrequency Ablation of Peripheral Nerves to Treat Pain Policy revision without position change
11/01/2019	Policy revision without position change
03/01/2020	Coding update
11/01/2020	Annual review. Policy statement and literature updated.
11/01/2021	Annual review. No change to policy statement. Policy guidelines and literature updated.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT (No changes)	
BEFORE	**AFTER**
Ablation of Peripheral Nerves to Treat Pain 7.01.154 **Policy Statement:** Radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered **investigational**. Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered **investigational**. Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered **investigational**. Ablation of peripheral nerves to treat pain is considered **investigational** in all other conditions, with the exception of facet joint pain.	**Ablation of Peripheral Nerves to Treat Pain 7.01.154** **Policy Statement:** Radiofrequency ablation (RFA) of peripheral nerves to treat pain associated with knee osteoarthritis or plantar fasciitis is considered **investigational**. Cryoneurolysis of peripheral nerves to treat pain associated with knee osteoarthritis or total knee arthroplasty is considered **investigational**. Radiofrequency ablation or cryoneurolysis of peripheral nerves to treat pain associated with occipital neuralgia or cervicogenic headache is considered **investigational**. Ablation of peripheral nerves to treat pain is considered **investigational** in all other conditions, with the exception of facet joint pain.